In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 31, 2022

RUBY KATHERINE GORDON, *Parent and natural guardian of* C.C., *a minor,*	*	PUBLISHED
Petitioner,	*	No. 18-431V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza ("flu") vaccine; Acute Disseminated Encephalomyelitis ("ADEM"); Motion to Dismiss.
Respondent.	*	

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for petitioner.
Camille Collett, U.S. Department of Justice, Washington, D.C., for respondent.

DISMISSAL DECISION[1]

On March 23, 2018, Ruby Katherine Gordon as parent and natural guardian of C.C., a minor, ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that her child, C.C. suffered from Acute Disseminated Encephalomyelitis ("ADEM") as a result of receiving an influenza ("flu") vaccination on October 30, 2015. Petition (ECF No. 1).

After a review of the record as a whole, including expert reports, medical records, and affidavits, and for the reasons set forth below, I find by preponderant evidence that the evidence

[1] In accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012), because this opinion contains a reasoned explanation for the action in this case, **this opinion will be posted on the website of the United States Court of Federal Claims**. This means the opinion will be available to anyone with access to the internet. As provided by 42 U.S.C. § 300aa-12(d)(4)B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). **If neither party files a motion for redaction within 14 days, the entire opinion will be posted on the website and available to the public in its current form.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

in this case demonstrates that C.C.'s condition began prior to receipt of the vaccination and thus was not caused by the vaccination.

I. Procedural History

On March 23, 2018, petitioner filed a petition and medical records alleging that her son, C.C., sustained ADEM caused by the flu vaccine administered to him on October 30, 2015. Petition at Preamble. On July 25, 2018, respondent filed a status report requesting additional medical records and stating his intention to continue to defend this case. Respondent's ("Resp.") Status Report ("Rept.") (ECF No. 9). On July 26, 2018, the court ordered petitioner to file the records identified in respondent's status report. (ECF No. 10). Petitioner filed the medical records between September 10, 2018, to February 19, 2019. (ECF Nos. 11, 16, 21).

On February 20, 2019, I directed respondent to file a status report outlining any additional records that were needed, and to summarize his opposition to informal resolution. (ECF No. 23). On April 3, 2019, respondent submitted a status report indicating that one medical record was missing and stating his intention to defend the case. (ECF No. 24). Respondent outlined that while petitioner alleges that C.C. suffered from ADEM, his headaches preceded the vaccination at issue, C.C. had not been diagnosed with ADEM, and C.C. had been diagnosed with attention deficit hyperactivity disorder ("ADHD") before the vaccination. *Id*. Respondent argues that the diagnosis of ADHD better explains the child's condition than a diagnosis of ADEM. Resp. Motion ("Mot.") to Dismiss at 7-8 (ECF No. 74). The petitioner disagrees. Petitioner's ("Pet.") Response at 5-6 (ECF No. 76).

On April 11, 2019, an initial status conference was held that outlined "several categories of records and issues" that petitioner needed to address. Scheduling Order (ECF No. 25). Specifically, I explained that one of the medical records indicated that C.C. had been in pre-school until October 2015, but then petitioner's affidavit stated that she picked C.C. up on November 9, 2015, from daycare. *Id.*; *See also* Pet. Affidavit ("Aff.") ¶ 4; Pet. Exhibit ("Ex.") 3 at 7. I explained that petitioner should "make further efforts to obtain any records that do exist from the facility or from the petitioner," regarding C.C.'s pre-school enrollment. Scheduling Order (ECF No. 25) at 2. Between May 2, 2019, and August 22, 2019, petitioner filed additional records. (ECF Nos. 26, 28, 37, 39, 41). I authorized petitioner to serve several subpoenas for records from the pre-school facility, Amazing Kids or its former owner, an individual named Ms. Stephanie Hopper. *See* Order, granting Motion to Issue Subpoenas. (ECF Nos. 34-35). On August 16, 2019, petitioner filed a Status Report stating she has been unable to obtain the requested daycare records from the permanently closed Amazing Kids Child Care Center. Pet. Status Rept. (ECF No. 38).

On August 28, 2019, a status conference was held, and I issued a Scheduling Order which ordered petitioner to file an expert report in support of vaccine causation, any additional medical records and affidavits, and for respondent to file a responsive expert report and Rule 4(c) following petitioner's expert report. (ECF No. 42).

On November 26, 2019, petitioner filed an expert report by Dr. Maria Fangchun Chen, a neurologist.[3] Pet. Ex. 30 (ECF No. 48). On March 20, 2020, respondent filed his Rule 4(c) report and an expert report by Dr. Peter M. Bingham, M.D.[4] Resp. Report ("Rept."); Resp. Ex. A (ECF No. 50). A Rule 5 Status Conference was held on May 6, 2020. I explained that a review of the petitioner's affidavits and the medical records raises a serious factual issue related to the onset of C.C.'s alleged vaccine injury. Rule 5 Order at 2 (ECF No. 52). I stated, "Within the Vaccine Program, there is a strong presumption that contemporaneous medical records are accurate," and that the "contemporaneous medical records are not missing information, they contain information that indicates C.C.'s headaches began prior to the vaccination and that his behavioral problems did as well.[5] These records represent a significant obstacle for petitioner's claim." *Id*. On June 9, 2020, petitioner filed a status report indicating her intention to file a supplemental expert report by Dr. Chen, and an affidavit from Stephanie Hopper, the owner of the daycare that C.C. attended. (ECF No. 57). On June 17, 2020, petitioner filed updated medical records. Pet. Exs. 32 & 33. (ECF No. 58).

On September 28, 2020, petitioner filed school records from Grace Academy, a supplemental Expert report by Dr. Chen, and medical literature. Pet. Exs. 34-36 (ECF No. 63). On December 23, 2020, petitioner filed a statement from Stephanie Hopper, former administrator of Amazing Kids Child Care Center. Pet. Ex. 37 (ECF No. 63). On February 25, 2021, respondent filed a status report indicating her intention to continue to defend the case and for the court to set a deadline for respondent to submit a motion to dismiss the case. (ECF No. 71). On July 12, 2021, respondent filed a motion to dismiss, asserting that C.C.'s symptoms began prior to the vaccination and thus could not have been caused by a response to the vaccine. Resp. Mot.

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[3] Dr. Chen is a Neurologist and Assistant Professor of Clinical Neurology at Penn Presbyterian Medical Center in Philadelphia, Pennsylvania. Pet. Ex. 31 at 1. She is currently licensed to practice Neurology in Pennsylvania. *Id*. at 2. Dr. Chen completed her undergraduate studies at Louisiana State University in May 1999. *Id*. Dr. Chen completed an MD/PhD at the University of Pennsylvania School of Medicine from August 1999 to May 2007. *Id*. at 1. Her postgraduate training included an internship in Medicine at the Hospital of the University of Pennsylvania from June 2007 to July 2008, and a residency in Neurology from July 2008 to July 2011. *Id*. From July 2011 to July 2013 Dr. Chen was an attending physician in the Department of Neurology at Albert Einstein Healthcare Network in Philadelphia, Pennsylvania. *Id*. Dr. Chen has taught neurology in various settings from 2011 to present. *Id*. at 2. Dr. Chen has presented once, published in peer reviewed journals three times, and has submitted one abstract. *Id*.

[4] Dr. Bingham is a Neurologist and Professor of Neurology & Pediatrics at the University of Vermont. Resp. Ex. B at 2. He is currently licensed to practice Neurology and Child Neurology in Vermont and New York. *Id*. Dr. Bingham completed his undergraduate degree in Biology from Harvard College in 1981 and completed medical school at the Columbia College of Physicians & Surgeons in 1987. *Id*. From June 1987 to June 1989 Dr. Bingham completed a residency in Pediatric Medicine at the Children's Hospital of Philadelphia, and a Neurology Residency from July 1989 to June 1992. *Id*. From July 1993 to June 1994 Dr. Bingham was a Research Fellow at the Muscular Dystrophy Association in Philadelphia. *Id*. Dr. Bingham has served as an instructor of clinical neurology, and assistant professor of neurology & pediatrics at the University of Pennsylvania School of Medicine. *Id*. More recently he was an associate professor and professor of Neurology and Pediatrics at the University of Vermont from July 2000 to March 2013, and March 2013 to present. *Id*. Dr. Bingham has received over 10 research grants and has published extensively in peer reviewed journals. *Id*. at 4-7. Additionally, Dr. Bingham has contributed book chapters, and participated in symposium proceedings, and other presentations. *Id*. at 7-12.

[5] While I used the word presumption in the status conference to illustrate the problem confronting the petitioner, the order was written prior to the Federal Circuit clarifying in *Kirby* that there is no presumption that medical records are accurate and complete *as to all the patient's physical conditions. See Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (emphasis added).

to Dismiss. On September 27, 2021, petitioner filed her response to the motion to dismiss. Pet. Response (ECF No. 76). On October 12, 2021, respondent filed a reply to the response to the motion to dismiss. Resp. Reply (ECF No. 77).

The matter is now ripe for decision.

II. Evidence Submitted

a. Petitioner's Medical Records

C.C. was born on May 2, 2011, and received routine childhood vaccinations. Pet. Ex. 1 at 1-3. The family history included a brother and maternal grandmother who suffered from "headaches/migraines." Pet. Ex. 8 at 31.

On March 28, 2014, petitioner brought C.C. to Dr. Williams, his primary care provider ("PCP"), with a complaint of a knot on his head that was getting bigger. Pet. Ex. 8 at 11. Dr. Williams diagnosed the knot as an epidermoid cyst [6] and recommended petitioner continue to monitor the lesion, but no treatment or surgery was recommended unless the lesion changed shape, size, or became painful. *Id*. at 15. On May 8, 2015, at a four-year well-child visit it was noted that C.C. "cannot dress self without help," and "socializes well with peers, behavior problems (minor and improving)…tantrums (improving)." Pet. Ex. 8 at 44.

C.C. received a flu vaccine at Shelby Children's Clinic on October 30, 2015. Pet. Ex. 1 at 2. There was no other record associated with that visit. On November 10, 2015, petitioner made a same day appointment for C.C. to see pediatrician, Dr. Christopher Cerjan. Pet. Ex. 2 at 24. The medical record reflects that C.C.'s chief complaint was "headaches x 1 month, cyst on back of head since 6 months of age." Pet. Ex. 2 at 22. The History of Present Illness ("HPI") provides:

> [C.C.] presents for headaches. He has had a cyst in his head for the past several years – noted at 6 months age when he was being seen by CaroMont Family [Medicine]. He has not had any imaging – had palpable mobile nodule on his left parietal-occipital area. He has been having headaches for the past month. His pain happens at various times during the day with variable duration. His activity is less when his head hurts…

Id.

Dr. Cerjan's diagnosis was "Chronic Headache." Pet. Ex. 2 at 25. His plan was: "Advised on sx [symptom] diary. Reassured about scalp adenopathy. Will do MRI for headaches." *Id*. That same day, Dr. Cerjan ordered an MRI. The order form included a handwritten note of "Head x 1 mo 3 per wk." Pet. Ex. 12 at 1.

[6] An epidermoid cyst is a benign bump beneath the skin. They can appear anywhere on the skin, but are most common on the face, neck, and trunk. Epidermoid cysts are slow growing and often painless, so they rarely cause problems or need treatment. Epidermoid cysts, Mayo Clinic.org, https://www mayoclinic.org/diseases-conditions/epidermoid-cysts/symptoms-causes/syc-20352701 (last visited on Aug. 30, 2022).

On November 20, 2015, twenty-one days following the vaccination, C.C. underwent an MRI with and without contrast. Pet. Ex. 12 at 1-13. The MRI identified multiple white matter T2 hyperintensities. *Id*. The radiologist's report of the November 20, 2015, MRI read:

> FINDINGS: There are multiple T2 hyperintensities noted in the bilateral subcortical white matter and deep white matter of the cerebral convexities with more substantial involvement of the bilateral frontal lobes though a smaller number are also seen in the bilateral parietal lobes. No significant involvement of the temporal or occipital lobes, brainstem or cerebellum, or the basal ganglia. The lesions sizes and shapes vary somewhat, they can be irregular, ovoid to rounded, and the largest measure up to 10 mm see left frontal lobe image 21 series 5. These are best seen on the FLAIR T2 imaging sequence. None of them appear to be associated with significant edema or mass effect. On T1 pre-contrast imaging there is very subtle decreased signal within the lesions, they do not enhance. There are periventricular lesions present, and it is possible there may be minimal involvement of the lateral portions of the corpus callosum, T2 sagittal or coronal sequence was not obtained. GRE sequence demonstrates no blooming affect to suggest old hemorrhage.

Pet. Ex. 15 at 5.

The radiologist's impression was as follows:

> IMPRESSION: 1. T2 hyperintense abnormalities seen within the white matter of the bilateral cerebral convexities with appearance as discussed in detail above. The differential diagnosis is long, given the lack of enhancement or mass effect, consider the possibility this represents the residua of old TORCH infection[7], a nonenhanced CT might be helpful at characterizing further as occasionally calcifications can be seen post infection. ADEM is a consideration, apparently the patient had a flu vaccine on 10/30/2015. Multiple sclerosis is felt unlikely given the patient's age.

Id. at 5-6.

C.C. had a consultation, with neurologist Herminia Ferreras, M.D. on December 16, 2015. Pet. Ex. 3 at 7. The reason for the visit was "abnormal MRI." *Id*. Under the "History of Present Illness," Dr. Ferreras wrote, [C.C.] is here with his parents and maternal grandmother. He is a pleasant 4 y/o without significant PMH (prior medical history) and with normal development history…here for further evaluation of abnormal behavior taken in 11/2015." *Id*. Dr. Ferreras also recorded, "The reason that led to brain MRI testing as mom indicated is – He was in Preschool this year and has to be pulled out by October 2015, because of behavioral problems. He has poor impulse control and started rubbing his head [in] the back. He also c/o of headaches, intermittent crossing his eyes. Mom also noticed that sometimes he is off

[7] A TORCH infection is a reference to the group of infections (toxoplasmosis, other agents, rubella, cytomegalovirus, herpes simplex) seen in neonates that occurs when organisms causing one of the infections cross the placental barrier; they all have similar symptoms in babies and may be clinically silent in mothers. *Dorland's Illustrated Medical Dictionary 33rd* ed. (2020) (hereinafter *Dorland's*) 1812, 1910.

balance…he is very emotional." *Id*. Dr. Ferreras reviewed the MRI and wrote that "Brain MRI showed white matter changes," and she repeated the impression from the MRI in her notes. *Id*.

Under impression and plan Dr. Ferreras noted "4 y/o with abnormal [white matter] in brain MRI can be finding in past infection, vs a demyelination condition from a progressive disease such as [metachromatic leukodystrophy], [adrenoleukodystrophy] or even lysosomal disease, neurocutaneous syndromes. Encouraging that he has not shown clear regression. He has headaches and personality changes which may or may not be related to his MRI findings." Pet. Ex. 3 at 10. The radiologist had noted that these diagnoses were unlikely given the location of the white matter process but were not excluded. Pet. Ex. 15 at 6. Dr. Ferreras suggested a follow up MRI, CT of the brain, lab work, and referral to ophthalmology. *Id*. at 10.

On December 28, 2015, C.C. underwent a head CT scan without contrast. Pet. Ex. 3 at 12. The findings included, "vague multifocal low attenuation is seen in the periventricular subcortical white matter [in] both cerebral hemispheres similar to the findings of previous MRI." *Id*. The impression included, "vaguely decreased attenuation seen in the periventricular subcortical white matter both cerebral hemispheres corresponding to the areas of abnormal signal seen on recent MRI. *No calcification is observed* within the areas of abnormality…pansinusitis with marked mucosal thickening and fluid left maxillary antrum, right ethmoid sinuses, and right sphenoid sinus." *Id*. at 12-13 (emphasis added).

C.C. had a subsequent medical appointment with Charlotte Eye, Ear, Nose and Throat Associates, on January 29, 2016. Pet. Ex. 11 at 3-5. The record noted the history of brain lesion on MRI, headaches one to two times a week, eyes crossing or drifting, getting worse, and the condition was intermittent and has been *going on for over four months*. *Id*. at 3 (emphasis added). He was diagnosed with hypermetropia (far sightedness) and astigmatism neither of which required treatment. *Id*. at 5.

On June 13, 2016, C.C. was evaluated at Shelby Children's Clinic for a five-year well-child visit. Pet. Ex. 2 at 11-14. Under history it was noted that C.C. "had significant behavior problems in pre-K with Vanderbilts + ADHD on teacher and parent forms. He will be starting K in the fall- possibly Grace. He has poor attention and is easily distracted. He is impulsive. He is emotional and does not do well with peers." *Id*. at 12. The diagnosis included "healthy 5 y/o WM with ADHD." *Id*. at 15. C.C.'s diagnosis was ADHD combined type, and the plan was to continue immunization per schedule and start him on a trial of Quillivant,[8] a medication to treat ADHD. *Id*.

A repeat brain MRI was performed on June 15, 2016. Pet. Ex. 6 at 156-157. The brain MRI findings included "stable nonspecific areas of abnormal white matter T2 hyperintensity most prominently involving the subcortical deep and periventricular white matter in the bilateral frontal lobes. There are no areas of abnormal contrast enhancement or restricted diffusion." Pet. Ex. 6 at 156. The impression notes, "once again these most likely represent areas of remote nonspecific white matter injury. The sequela of chronic ischemic microvascular disease, vasculitis or demyelinating disease process are difficult to exclude." *Id*. The medical records do

[8] Quillivant-a central nervous system stimulant used for the treatment of ADHD, Drugs.com, https://www.drugs.com/quillivant-xr.html (last visited Aug. 26, 2022).

not demonstrate that C.C. was examined by Dr. Ferreras on this date. *Id*. According to petitioner's health insurance statement, C.C. was assigned the diagnostic code of G37.9 which stands for "demyelinating disease of the central nervous system, Unspecified" and "R51" which stands for "headache." Pet. Ex. 5 at 5-6.

Subsequent medical care was relatively sparse. C.C. had pediatric well visit appointments, most of which were focused on his diagnosis of ADHD. *See* Pet. Ex. 4; Pet. Ex. 23. On June 14, 2017, C.C. was seen by Dr. Cerjan for his six-year well child exam. Pet. Ex. 23 at 14-18. The history noted that C.C. was doing well except he was "having a lot of anxiety," was homeschooled using a virtual academy, and had a "major breakdown with even one [day] at Grace Christian." *Id*. at 14. C.C.'s physical exam was normal, and diagnosis included ADHD, combined type. *Id*. at 17. On August 24, 2017, C.C. had an appointment for an "ADD recheck." Pet. Ex. 4 at 2. At this appointment, it was noted that C.C. was taking Quillivant, and his mother was trying to adjust the dosage. *Id*. C.C.'s neurological exam noted that he was, "awake, alert, level of consciousness is appropriate for age, normal strength." *Id*. He was also "cooperative," and had "appropriate affect." *Id*. C.C.'s diagnosis of ADHD continued.

On February 26, 2018, C.C. was seen by neuropsychiatrist, Dr. C. Thomas Gualtieri. Pet. Ex. 19 at 10. Dr. Gualtieri wrote:

> C.C. is 5-years old and is schooled at home. He has been healthy. No chronic medical problems. Immediately following a flu-shot, he started having headaches in 2014; they saw Dr. Perreiras [sic] and he had a comprehensive work up, including genetic testing, two MRIs and a neuropthalmologist. He has lesions in the frontal and occipital lobes that are believed to be related to the flu shot. He has been treated with neurofeedback for headache, impulsivity. His primary care provider diagnosed attention deficit disorder and they tried Quillivant, Focalin, and Adderall and they all make him aggressive, he wouldn't sleep or eat.[9]

Id.

Dr. Gualtieri wrote that, "The clinical picture is one of attention deficit/hyperactivity disorder, but atypical attention deficit/hyperactivity disorder in a very smart child. It may or may not be related to brain injury. He needs a formal neuropsychological test battery after he turns seven." *Id*. Dr. Gualtieri recommended that C.C. try guanfacine. *Id*. at 11.

C.C. had a follow-up appointment with Dr. Gualtieri on March 8, 2018. Pet. Ex. 19 at 8. C.C. was described as "a cheerful, healthy and bright child who is hyperactive and disinhibited in the clinic." *Id*. His mother reported that he was doing well on 1 mg of Tenex[10] and it helps him with his lessons in the morning. *Id*. However, by 2-3 pm, C.C.'s hyperactivity and

[9] This record contains multiple errors. The flu shot referenced was given in October 2015, not 2014. Further, no lesions in the occipital lobe of the brain were identified on the MRI. Additionally, C.C. was born on May 2, 2011, and thus was six and half at the time of this medical appointment.

[10] The generic name for Tenex is guanfacine hydrochloride. It is used to treat high blood pressure, but has an off label use for the treatment of ADHD. Healthline.com, https://www healthline.com/health/adhd/tenex-adhd (last visited on Aug. 26, 2022).

impulsiveness starts to come back. *Id*. Dr. Gualtieri also noted that C.C. did well on the tests and his exam was "quite normal but he is disinhibited and into everything." *Id*.

On June 7, 2018, C.C. had another appointment with Dr. Gualtieri. Pet. Ex. 19 at 6. At this appointment, under "Chief Complaint," it read: [C.C.] is a 7-year-old white male who has brain injuries related to vaccination injection." *Id*. Dr. Gualtieri noted that C.C. was on one mg of Tenex at night "and he is doing very well." *Id*. It was recommended that C.C. have a follow-up appointment in three months. *Id*. Aside from the change in the "Chief Complaint" section, the medical record was almost identical to the previous two records from appointments with Dr. Gualtieri.

On July 17, 2019, C.C. was seen by Dr. Cerjan for his 8-year well child exam. Pet. Ex. 27 at 5-6. The history noted that C.C. was "making A/Bs in the 2nd grade – now in regular school…doing well with peers." *Id*. at 5. His ADHD diagnosis was noted as stable with a refill of Guanfacine, a medication to treat ADHD. *Id*.

No other medical records were filed.

b. C.C.'s School Records

C.C.'s educational history was mentioned throughout the medical records and Ms. Gordon's two affidavits. Petitioner stated that C.C. had been attending Amazing Kids Childcare since he was seven months old. Pet. Ex. 29 at 6. In her affidavit, petitioner also stated that since C.C.'s headaches which began in November 2015, he became more aggressive and "even pushed over a small bookcase at preschool." She stated that C.C. was unenrolled in preschool at Amazing Kids in November 2015 and that the preschool closed in December 2015.

After considerable effort, petitioner was able to obtain a statement, dated November 12, 2020, from Ms. Stephanie Hopper, the administrator of Amazing Kids Child Care Center that C.C. had attended. Pet. Ex. 37. Ms. Hopper stated that, "All records of enrollment, withdrawing, attendance, and discipline were all given to parents when the childcare center closed in December 2015." *Id*. She also stated:

> The months leading up to December, [C.C.] did withdraw from Amazing Kids Child Care Center and enrolled at Grace Christian Academy in Kings Mountain. From my memory, he left during the month of October 2015 to attend Grace Christian Academy. Based on my memory, [C.C.'s] mother moved him to Grace Christian Academy because of his behavior, mother wanted to see if they could help with his behavior issues. As far as his behavior goes, I do not recall exact dates due to no longer having any records from Amazing Kids Child Care Center, again these were all given to mother at time of closure in December 2015. From memory, his behavior would consist of anger outrages, throwing chairs, cussing. To my knowledge [C.C.] did not have any medical issues that would have impacted his attendance in October or November 2015. Records were kept of major behavioral issues along with verbal conversations with parents in reference to children's behavior. All written records were given to parents at time of child-care center closure in 2015.

Id.

When C.C. was seen by Dr. Ferreras on December 16, 2015, the History of Present Illness stated, "….the reason that led to brain MRI testing as mom indicated is-He was in Preschool this year and had to be pulled out by October 2015, because of his behavioral problems…." Pet. Ex. 3 at 7.

Petitioner filed other limited school records from 2016 and 2017. Pet. Ex. 34. These include "North Carolina Virtual Academy" records that have a start date of August 22, 2016 and go through June 2017, representing C.C.'s kindergarten year. *Id*. at 9-14. He appears to have done quite well with high grades in most subjects that year.

Additionally, petitioner filed an application to Grace Christian Academy which was for the 2017-2018 school year. *Id*. at 2-6. However, no other records associated with Grace Christian Academy have been filed.

On the February 26, 2018, Dr. Gualtieri, noted that C.C. "is 6-years-old and is schooled home." Pet. Ex. 19 at 10. Further, under "Treatment Plan," Dr. Gualtieri referenced how C.C. could only do 17 days of school this year (2017-2018). According to petitioner's second affidavit, C.C. was able to start school for 2nd grade. Pet. Ex. 29. at ¶ 9.

c. Petitioner's Affidavits

Petitioner, mother of C.C. submitted two affidavits, the first was filed on March 23, 2018, and the second was submitted on October 28, 2019. Pet. Aff. (ECF No. 1); Pet. Ex. 29; (ECF No. 45). In her second affidavit, petitioner stated that "C.C. did not have headaches or behavioral problems prior to his vaccination on October 30, 2015." Pet. Ex. 29 at ¶ 2. Prior to the vaccination, C.C. "had a small scalp cyst on his head," and petitioner took him to the doctor for pain specific to that nodule. *Id*. at ¶ 3. She explained that "he did not have headaches but pain on that spot on the back of his head." *Id*. Petitioner stated that C.C. received the influenza vaccine on October 30, 2015. *Id*. at ¶ 4.

Petitioner stated that all was normal until on Monday, November 9, 2015, when she picked him up at Amazing Kids at approximately 5:00pm, "he began to experience severe headaches, and he complained of an actual all over headache." Pet. Ex. 29 at ¶ 5. He had been "having headaches for a day or two, but it wasn't until November 9. 2015 that they became severe." Pet. Aff. at ¶ at 4; Pet. 2nd Aff. 29 at ¶ 5. Petitioner stated, "his eyes were doing something weird and his behavior was off." Pet. Ex. 29 at ¶ 5. The following day, November 10, 2015, petitioner was able to get C.C. a same day appointment with his pediatrician and stated that she informed the pediatrician that he had been "having severe headaches since the day prior." Pet. Aff. at ¶ 4; Pet. Ex. 29 at ¶ 5.

Petitioner explained that Dr. Cerjan was a new doctor and was given a lot of information "in regard to the nodule on the back of his head and the specific pain to that area while presenting that day with an all over headache." Pet. Ex. 29 at ¶ 6. The doctor ordered an MRI for

CC. *Id*. Petitioner stated that, "[C.C.'s] headaches continued and his behavior became aggressive. He even pushed over a small bookcase at preschool. He was so mean to one of the teachers she quit." *Id*. Petitioner stated that she withdrew C.C. from the preschool in November 2015, and the preschool closed in December 201[5]. *Id*.

Petitioner explained that in the fall of 2016, C.C. attended "one day of Kindergarten and due to behavior could not go back." Pet. Ex. 29 ¶ 7. She stated that "The day he went, he lasted an hour." *Id*. In 2017 C.C. tried first grade and he made it 17 days because of his behavior, "he had become physically aggressive towards staff and property." *Id*. at ¶ 8. Petitioner stated that "he was unable to attend school," and as a result petitioner had to quit her "full time job with benefits to care for him and home school him." *Id*.

C.C. started second grade in 2018 and was in third grade in 2019. Pet. Ex. 29 at ¶ 9. Petitioner stated that C.C. "still struggles with emotional regulation and impulsivity, overall he is doing much better as he gets older. He has attended physical therapy and received neurofeedback." *Id*. Petitioner explained that C.C.'s primary care doctor was unsuccessful at finding medication, so petitioner drove him four hours to a specialist, who was able to prescribe medication "to help with the emotional regulation and impulse control." *Id*.

d. Petitioner's Expert Reports from Dr. Maria Fangchun Chen

Dr. Maria Fangchun Chen, a neurologist, filed two expert reports in this case. Pet. Ex. 30; Pet. Ex. 35 (ECF Nos. 48, 60). In her initial expert report Dr. Chen stated, "With my review of the images of the MRI brain dated 11/20/2015 and 06/15/2016 of C.C. and my review of the 27 exhibits of medical records, it is my expert medical opinion that these 2 MRI brain studies and his medical records support a diagnosis of a central nervous system demyelinating condition such as ADEM." Pet. Ex. 30 at 8. Dr. Chen observed that C.C.'s treating neurologist, Dr. Ferreras, assigned the diagnostic code of G37.9 to C.C.'s MRI dated 06/15/2016, which "stands for "Demyelinating Disease of the Central Nervous System, Unspecified." *Id*. Dr. Chen stated, "Hence, I conclude that Dr. Herminia Ferreras also diagnosed C.C. with a demyelinating central nervous system disorder such as ADEM." *Id*.

Dr. Chen stated that, "The only preceding immune trigger to an immune-mediated condition such as ADEM is the flu vaccination on 10/30/2015," and observed that C.C. had no symptoms of a cough, runny nose, fever or diarrhea that would support a preceding viral syndrome at his pediatric appointment on November 10, 2015. *Id*. In her second report, Dr. Chen stated that "the medical record documenting onset of symptoms noted by the medical providers as before the vaccination is problematic." Pet. Ex. 35 at 1. Dr. Chen stated, "The source of the onset of the headaches as being 1 month appears to have originated by intake staff…who does not have any notations to her name to indicate medical training," citing to C.C's first appointment post-vaccination on November 10, 2015. *Id*. She asserts that this notation is then "pulled into" Dr. Cerjan's notes for the same appointment and "Dr. Cerjan's notes do not document any attempts to further delineate the onset of the headaches as to the exact date. This raises the possibility that [Dr. Cerjan] simply propagated any information provided at intake without probing for the accuracy of the onset." *Id*.

Dr. Chen also asserted that the medical record from C.C.'s appointment with Dr. Ferreras contains errors, likely due to the use of Dragon voice recognition software. Pet. Ex. 35 at 2. Dr. Chen noted that one error that likely arose from the use of the Dragon voice recognition software was that the word "behavior" was substituted for "MRI." *Id.* The History of Present Illness provides, "[C.C.] is a pleasant 4 y/o without significant PMH and with normal development history is here for abnormal *behavior* taken in 11/2015." *Id.* at 22; Pet. Ex. 3 at 7. Dr. Chen stated that "behavior" cannot be "taken on 11/2015" as an MRI can be, and thus the word "behavior" under History of Present Illness, was a mistake. Pet. Ex. 35 at 2. Dr. Chen asserts that it is plausible that the Dragon voice recognition technology "misrecognized the word 'October' for 'November' in the note which stated that C.C. was pulled out of preschool by October 2015." *Id.* Then Dr. Chen stated that she was raising the issue that "physician histories at times cannot be trusted to be completely accurate, particularly when they lack details on the sequence of events," based on her personal experience of "witnessing my colleagues generate medical histories from referring physician's clinical notes without re-verification of the information from the patient due to time constraints of busy clinical practices." *Id.* at 2.

Dr. Chen relied mostly on C.C.'s two brain MRI studies dated November 20, 2015, and June 15, 2016, to provide her opinion about C.C.'s diagnosis. *Id.* at 4. She highlighted the most obvious areas of abnormalities from a T2 FLAIR series and explained that "these T2-hyperintense areas of white matter are typical of demyelination see[n] in ADEM. These T2 FLAIR hyper-intensities remained stable in the subsequent MRI study on June 15, 2016." *Id.* at 4-6. Dr. Chen wrote, "the white matter changes that I have highlighted in both MRI brain studies are typical of the white matter lesions that are found in MRI brain scans of children with ADEM." *Id.* at 7. Dr. Chen cited to an article by *Krupp et al.*, which provides diagnostic criteria for ADEM and explains that the MRI should demonstrate "diffuse, poorly demarcated, large (>1-2 cm) lesions involving predominantly the cerebral white matter." Pet. Ex. 30 at 7; Pet. Ex. 31B.[11] The *Krupp* paper also explains that for a diagnosis of ADEM there must be, "no new clinical or MRI findings that emerge three months or more after the onset [and] brain MRI is abnormal during the acute (three month) phase." *Id.* The article stated that, "The clinical features subsumed under the term ADEM typically follow a monophasic disease course," and that "The clinical symptoms and radiologic findings of ADEM can fluctuate in severity and evolve in the first three months following disease onset." *Id.* at 3. Dr. Chen observed that C.C.'s second MRI, taken in June 2016, was stable, and that C.C.'s course followed a monophasic illness without further accumulation of changes on the second brain MRI. Pet. Ex. 30 at 7.

Dr. Chen also stated that the "diagnosis of ADEM is typically achieved when symptoms of headache or altered mental status or behavior results in brain imaging with MRI. Pet. Ex. 30 at 7. In her second report, she stated that "behavioral changes in pediatrics have been accepted as mild encephalopathy." Pet. Ex. 35 at 2. She wrote, "Acceptable cognitive changes that constitute encephalopathy may range from "irritable" (mild) to "coma" (severe)." *Id.* Dr. Chen cited to an article by *Fridinger & Alper*, which reviewed medical charts of 25 children diagnosed

[11] Lauren B. Krupp, et. al., *International Pediatric MS Study Group criteria for pediatric multiple sclerosis and immune mediated central nervous system demyelinating disorders: revision to the 2007 definition*, 19(10) Multiple Sclerosis J., 1261-1267 (2013). [Pet. Ex. 31B-1]

with ADEM to understand how encephalopathy was being documented. *Id.*; Pet. Ex. 36.[12] The authors found "irritability (36%), sleepiness (52%), confusion (8%), obtundation (20%), and coma (16%) as encephalopathy-defining features in ADEM." Pet. Ex. 36 at 1; Pet. Ex. 35 at 3. Dr. Chen stated that, "behavioral changes such as irritability are not unlikely as a presentation of encephalopathy as part of the diagnostic criteria for ADEM." Pet. Ex. 35 at 3.

Dr. Chen stated that "ADEM is an immune mediated disorder in which an individual's immune system inappropriately targets the nervous system after a provoking factor." Pet. Ex. 30 at 7. She stated that, "The concept of molecular mimicry has been proposed, but cannot be proven, for the majority of immune-mediated central nervous system [diseases]." *Id.* Dr. Chen wrote, "The timing of the onset of neurological symptoms can range from days to weeks and this range is expected due to the biological variability of the immune response across the human population. Several studies demonstrate that typical onset of ADEM is within a month from the initial infection or vaccination." *Id.*

To support her theory of vaccine causation, Dr. Chen cited to an article by *Karussis & Petrou,* which examined post-vaccination inflammatory CNS demyelinating syndromes that were reported in the medical literature. Pet. Ex. 31-J.[13] The article described ADEM as "an inflammatory demyelinating disease of the central nervous system," that "is a rather rare disease." *Id.* at 2. Further, the authors described ADEM as "monophasic" in the majority of patients, and if relapse occurs, it usually happens within 3 months from its onset." *Id.* The article explained, that "the current pathogenetic hypothesis in post-vaccination ADEM is that antigens of viral origin cross-react with myelin components (molecular mimicry) and in a secondary manner induce a hyperergic[14] reaction, that leads to the development of disseminated demyelination." *Id.* at 87.

Dr. Chen concluded that C.C.'s MRI demonstrated lesions that are typical of ADEM and that ADHD "cannot be the diagnosis to explain the white matter changes on the MRI which do not appear in ADHD." She also noted that ADHD was not listed in the radiologist's differential. Instead, she opined that ADHD can be a secondary diagnosis due to a primary central nervous system injury such as ADEM. Pet. Ex. 30 at 8. It was her opinion that C.C.'s ADEM was caused by the flu vaccination, and that the "onset of behavioral problems after the flu vaccination indicates that ADHD likely is a result of brain injury caused by the ADEM, and not due to any hereditary disorder." *Id.*

Dr. Chen concluded that C.C.'s diagnosis is ADEM, based on the medical records, including a review of the two MRIs and the other evidence submitted. Pet. Ex. 30; Pet. Ex. 35 at 3.

e. Respondent's expert opinion of Dr. Peter Bingham

[12] Fridinger, S.E. & Alper, Gary, *Defining Encephalopathy in Acute Disseminated Encephalomyelitis,* 29 J. of Child Neurol. 751-755 (2014).

[13] Karussis, D. and Petrou, P., *The spectrum of post-vaccination inflammatory CNS demyelinating syndromes,* 13 Autoimmunity Reviews, 215-224 (2014). [Pet. Ex. 31-J].

[14] Hyperergic is an increased sensitivity in allergy. *Dorland's* at 877.

On March 20, 2020, respondent filed an expert report by Dr. Peter M. Bingham, a pediatric neurologist. Resp. Ex. A (ECF No. 50). Dr. Bingham opined that C.C.'s medical records weigh against vaccine causation for three reasons: timing, relevant condition, and theory. *Id*. at 2-3. Dr. Bingham argued that the clinical course outlined in the medical records indicates "that the symptoms that Petitioner attributes to vaccination on 10/30/15 more likely than not began prior to vaccination." *Id*. Dr. Bingham contended that C.C.'s relevant condition and clinical course "does not support the diagnosis of ADEM based on published criteria," and that the "available evidence does not support a conclusion that influenza vaccination causes brain lesions, ADD, ADHD, or ADEM." *Id*. at 3.

Regarding timing, Dr. Bingham pointed to "at least four different notes from different medical providers in C.C.'s contemporaneous medical records that consistently report the presence of headaches and behavioral changes *prior to* vaccination." Resp. Ex. A at 4. Specifically, Dr. Bingham refers to the pediatric visit on November 10, 2015, which indicates that C.C. had headaches for one month; the MRI request form from November 20, 2015, which indicates headaches for one month, with three per week; the neurological evaluation from December 16, 2015, which indicates that because of C.C.'s behavioral problems he had to be pulled out of school in October 2015; and finally, the note from the appointment with the ENT in January 2016 that indicated C.C.'s eyes were crossing for over four months." Resp. Ex. A at 4; *see also* Pet. Ex. 18 at 32; Pet. Ex. 12 at 1; Pet. Ex. 3 at 7; Pet. Ex. 11 at 3. Dr. Bingham concluded, "Taken together, these notes in the medical record strongly support symptom onset prior to vaccination." Resp. Ex. A. at 1. Dr. Bingham correctly observed that Dr. Cerjan's notes from the November 10, 2015, appointment, do not indicate that C.C.'s headaches began post flu vaccination, instead he stated on November 10, 2015, that C.C. "has been having headaches for the past month," which dates the onset of C.C.'s headaches to weeks before the vaccination at issue. *Id*.

Dr. Bingham also argued that C.C.'s clinical course does not support the diagnosis of ADEM based on the published criteria for ADEM. Resp. Ex. A at 3. Dr. Bingham referred to an article, filed by petitioner, by *Cole et al.*, which reviewed the diagnostic criteria for ADEM as defined by the International Pediatric Multiple Sclerosis Society Group ("IPMSSG") in 2007, updated in 2013. Resp. Ex. A at 3; Pet. Ex. 31-M.[15] The article states that the International IPMSSG's ADEM criteria requires among other things, "Encephalopathy *not* explained by fever, systemic illness, or postictal symptoms." Pet. Ex. 31-M at 2. Dr. Bingham observed that the article also states, that, "All children must have some component of encephalopathy during their acute illness to meet the IPMSSG criteria for ADEM." Resp. Ex. A at 9; Pet. Ex. 31-M at 2. However, *Cole* also acknowledged that "data regarding the spectrum of encephalopathy in patients with ADEM are limited." Pet. Ex. 31-M at 3. Dr. Bingham wrote, "Based on my own experience as a pediatric neurologist, I would not consider either headache or difficult behaviors of attention deficit disorder as evidence of encephalopathy, and there is no other evidence in the records that C.C. suffered encephalopathy in the days or weeks following vaccination." Resp. Ex. A at 4.

[15] Jordan Cole, et. al., *Acute Disseminated Encephalomyelitis in Children: An Updated Review based on Current Diagnostic Criteria*, 100 Pediatric Neurology 26-34 (2019). [Pet. Ex. 31M].

Regarding the white matter lesions seen on the MRI from November 20, 2015, Dr. Bingham agreed with the neuroradiologist who interpreted the findings that they were non-specific. Resp. Ex. A at 4. Dr. Bingham argued that the findings on C.C.'s MRI could be "due to a number of different possible underlying causes," including a "radiologically isolated syndrome ("RIS")." Resp. Ex. A at 3. He defined RIS by referring to an article by *Makhani* as a "situation wherein presumptively demyelinating lesions in the white matter are discovered *incidentally* on brain MRI, when subjects undergo MRI for reasons not related to brain demyelination."[16] Resp. Ex. A at 3; Resp. Ex C at 1. The *Makhani* article reported that out of the 38 children with "RIS" identified on their MRIs, nearly half developed a first clinical event consistent with demyelination and an even higher proportion developed radiologic evolution." Resp. Ex. C at 5. Dr. Bingham asserted that the *Makhani* article demonstrated that "the scenario of incidental, apparently demyelinative, lesions on brain MRI is increasingly encountered." Resp. Ex. A at 3. Dr. Bingham argued, "In clinical laboratory or radiological diagnosis when the probability of a finding related to the clinical precipitating symptom is relatively low, one has to consider the possibility of un-related findings such as RIS." Resp. Ex. A at 3-4. He suggested that a spinal tap would have been helpful to determine if C.C.'s lesions were actively demyelinating. *Id*. at 4. However, Dr. Bingham agreed with Dr. Chen that the white matter hyperintensities seen on the MRI are typical of those seen in ADEM but observed that "they are non-specific as to etiology, and not pathognomonic of ADEM." *Id*. at 5. Dr. Bingham contended that occurrence of encephalopathy in conjunction with the white matter lesions is central to the diagnosis of ADEM, which Dr. Chen contended that "when symptoms of a headache or altered mental state or behavioral changes lead to an MRI which shows demyelination, can support a diagnosis of ADEM."

Additionally, Dr. Bingham noted that there is a family history of ADHD with two of C.C.'s siblings, and he opined that this family history also represents an alternative or contributor to ADHD in this specific case. Resp. Ex. A at 5; Pet. Ex. 3 at 7. He also stated that C.C.'s father and maternal grandfather were said to have anger/psychiatric problems, and it is also possible that C.C. "suffered mood dysregulation or anger problems on either a genetic of environmental (learned) basis." Resp. Ex. A at 5; Pet. Ex. 3 at 7; Pet. Ex. 6 at 172.

Finally, Dr. Bingham disagreed with Dr. Chen's opinion regarding vaccine causation. Resp. Ex. A at 5. Dr. Bingham argued that Dr. Chen's theory relies "on an incorrect temporal onset of C.C.'s symptoms to attribute causation to the influenza vaccine." Resp. Ex. A at 5. Dr. Bingham noted that even if no other underlying cause can be determined for an ADHD diagnosis, it "may wax and wane in the severity of symptomatology in relation to other life events…and is itself a polygenic, hereditary disorder…that appears to affect multiple family members across generations." *Id*. Dr. Bingham concluded his report by stating that in his medical opinion, "C.C. does not have ADEM…and more likely than not, C.C.'s headaches, behavioral problems, ADHD, and/or ADD are unrelated to his receipt of the flu vaccination on 10/30/15.' *Id*.

[16] Naila Makhani, et. al., *Radiologically isolated syndrome in children: clinical and radiologic outcomes*, 4(6) Neurology Neuroimmunology & Neuroinflammation, e395 (2017). [Resp. Ex. C].

III. Legal Standard

To receive compensation under the Vaccine Act, a petitioner must prove by a preponderance of the evidence that the injury was caused by the vaccine. § 300aa-13(a)(1). To be compensated, the petitioner must establish a causal link between the vaccination and the injury. It may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table." § 300aa-13(a)(1)(A); § 300aa-14(a). If the injury is not listed in the Vaccine Injury Table, a petitioner must prove actual causation or causation in fact by a preponderance of the evidence. § 300aa-11(c)(1)(C(ii); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). In this case, petitioner is not alleging that C.C. suffered a Table injury, but that he suffered a new onset neurological disorder caused by the flu vaccination he received on October 30, 2015.

Petitioners cannot establish entitlement to compensation based solely on their assertions. Rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 300aa-13(a)(1). In determining whether petitioners are entitled to compensation, the special master shall consider all material contained in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 300aa-13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' offered experts and rule in petitioners' favor when the evidence weighs in their favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); *Althen*, 418 F.3d at 1280 ("close calls" are resolved in petitioner's favor).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. Further, there is no presumption that medical records are complete as to all of a patient's conditions. *Kirby v. Sec'y of Health & Human Servs.,* 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs.,* No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). And, importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence

of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

a. Parties' arguments related to the onset of C.C.'s condition

Respondent, in his motion to dismiss, argues, "the contemporaneous medical records filed by petitioner in support of her petition document that C.C.'s symptoms predate the vaccination, and thus, C.C.'s alleged injury could not have been caused by the vaccine." Resp. Mot. at 7. Respondent avers that "C.C.'s behavioral problems were documented in the medical records as ongoing for at least six months prior to vaccination," and that "C.C.'s headaches also predated the vaccine by at least one month." *Id.* Additionally, respondent asserts that petitioner's affidavits also contradict the medical records and the letter from C.C.'s former pre-school administrator, Ms. Stephanie Hopper. *Id.*

Petitioner argues that C.C.'s symptoms did not predate the vaccination. Pet. Response. at 4. Petitioner asserts that the medical records, specifically the appointment from November 10, 2015, is inaccurate as to the onset of C.C.'s headaches. *Id.* Petitioner states her expert, Dr. Chen "cautions against the reliability of the medical record for the purposes of establishing onset of symptoms," and that Dr. Chen observed that "Dr. Cerjan's notes do not document any attempts to further delineate the onset of [C.C.'s] headaches as to the exact date or contextualize the headaches in the setting of C.C.'s parietal-occipital cyst, which had been present since 6 months of age." *Id.* Petitioner argues that her affidavits clarified that C.C. complained about pain on the spot of the back of his head, referring to the cyst prior to the vaccination, and not the headache. *Id.* Further, petitioner argues that the November 10, 2015, record is inconsistent with the March 8, 2018, record, where petitioner provided a history of headaches beginning after the flu vaccine. *Id.* at 4; *see also* Pet. Ex. 19 at 8.

Finally, petitioner argues that respondent's assertion that C.C.'s behavioral issues that were documented six months prior to the vaccination is not evidence of encephalopathy. Pet.

Response at 5. While petitioner acknowledges that C.C.'s behavioral issues were documented as early as May 2015, she also "stresses the importance of differentiating between an altered mental state and poor behavior." *Id.* Petitioner asserts that "specific indications of an altered mental state due to encephalopathy such as crossing eyes and poor balance were not documented until after C.C.'s vaccination." *Id.* Petitioner submits that C.C.'s ADHD may have been a pre-existing condition prior to the flu vaccination, but that it worsened as a result of ADEM caused by the flu vaccine." *Id.* at 5. Petitioner concludes that "ADHD in the setting of ADEM presents a complicated clinical picture such as this one but should not result in a dismissal of petitioner's post-vaccination claim." *Id.*

Replying to petitioner's filing, respondent states that "petitioner appears to concede that C.C. has ADHD and that onset of his ADHD more likely than not predated the vaccination." Resp. Reply at 1. Respondent argued that C.C. was never diagnosed with ADEM and the medical records do not support a diagnosis of ADEM. Resp. Reply at 2. Respondent concludes that "the contemporaneous medical records filed by petitioner in support of her petition document that C.C.'s symptoms more likely than not predated the vaccine, and thus, C.C.'s alleged injury could not have been caused by the vaccine." *Id.* at 2. Respondent accordingly requests that the Special Master dismiss the petition. *Id.*

b. Discussion and conclusion regarding the onset of C.C.'s neurologic condition

The critical and dispositive issue raised by respondent is the onset of C.C.'s neurological condition. If the onset of C.C.'s neurological symptoms occurred prior to the vaccination, then the vaccination could not have been the cause of his neurological condition. Resp. Mot. at 1. However, if C.C.'s neurological symptoms began after the vaccination, as petitioner argues, then petitioner would have to demonstrate that the vaccine was the cause-in-fact of the alleged neurological condition.

Petitioner, through Dr. Chen, argued that the correct diagnosis for C.C. is ADEM. Pet. Ex. 30 at 8; Pet. Ex. 35. Dr. Chen stated that, "The diagnosis of ADEM is typically achieved when symptoms of headache or altered mental status *or* behavior results in brain imaging with MRI. MRI findings of T2 hyper-intense white matter lesions that signify white matter brain injury are typical of ADEM and other central nervous system demyelinating conditions…." Pet. Ex. 30 at 7. She stated that her review of C.C.'s two MRIs from November 20, 2015, and June 15, 2016, support a diagnosis of a central nervous system demyelinating condition such as ADEM." *Id.* at 8. Dr. Chen also asserted that C.C.'s headaches and behavioral issues can be evidence of mild encephalopathy in pediatric patients and stated, "often times, the diagnosis of mild encephalopathy is accepted retrospectively based on spinal fluid testing demonstrating inflammatory changes." Pet. Ex. 35 at 2. However, she acknowledged that no spinal fluid testing was done in C.C. *Id.*

Dr. Bingham disagreed with the Dr. Chen's diagnosis of ADEM. Resp. Ex. A at 4. Dr. Bingham argued that behavioral issues and headaches were documented in the medical records as beginning prior to the October 30, 2015 vaccination, and that the headaches and behavioral changes are not evidence of encephalopathy, required to make the diagnosis of ADEM. *Id.* at 4. However, he agreed with Dr. Chen that the findings on C.C.'s MRIs of "white matter

changes…highlighted in both MRI brain studies are typical of white matter lesions that are found in MRI brain scans of children with Acute Disseminated Encephalomyelitis ("ADEM")." Resp. Ex. A at 5. Dr. Bingham argued that the headaches and behavioral issues that C.C. had were related to his diagnosis of ADHD, not ADEM, and they began prior to the vaccination at issue in this case.

The article by *Fridinger & Alper*, referenced by Dr. Chen, explained that the IPMSSG defined encephalopathy as "one or more of the following: behavioral change, e.g., confusion, excessive irritability; alteration of consciousness, e.g. lethargy, coma." Pet. Ex. 36 at 4. Additionally, the authors explained that younger children diagnosed with ADEM, tended to have mild encephalopathy, defined as irritability and/or sleepiness. *Id*. They noted that irritability and/or sleepiness is a less objective measure, illustrating the challenge of diagnosing encephalopathy in younger children. *Id*. This article supports Dr. Chen's opinion that signs of encephalopathy in a child can be behavioral change, similar to the behavioral changes that are noted in C.C.'s medical records and the letter from Ms. Stephanie Hopper.

For the purposes of this decision, I accept Dr. Chen's opinion that behavioral issues can be evidence of mild encephalopathy, necessary for the diagnosis of ADEM and that C.C. likely had ADEM. However, based on a review of the medical records submitted, the affidavits by petitioner, and the letter from Amazing Kids administrator Ms. Stephanie Hopper, I find by preponderant evidence that C.C.'s symptoms of mild encephalopathy began prior to the receipt of the October 30, 2015, influenza vaccination, and thus could not have been caused by the vaccine.

Petitioner, in her affidavits and petition, alleged that C.C.'s headaches were the first symptom of his ADEM, which began approximately two days prior to November 9, 2015. Pet. Aff. at ¶ 4; Petition at ¶ 4. In her first affidavit, petitioner stated, "On Monday, November 9, 2015, at approximately 5:00 pm, I picked [C.C.] up from daycare at which time he began to experience severe headaches. He had been having headaches for a day or two, but it wasn't until November 9, 2015, that they became severe." Pet. Aff. at ¶ 4. In her second affidavit, petitioner clarified that C.C. complained "of an actual all over headache," and that "his eyes were doing something weird and his behavior was off." Pet. Ex. 29 at ¶ 5.

However, multiple contemporaneous medical records contradict petitioner's account of the onset of C.C.'s neurological symptoms. C.C.'s first three medical appointments after his October 30, 2015, vaccination, put onset of his headaches and behavioral issues before his vaccination. On November 10, 2015, C.C. had an appointment with Dr. Cerjan for "headaches for one month, cyst on back of head since 6 months of age." Pet. Ex. 2 at 22. Under "History of Present Illness," it notes that "[C.C.] has been having headaches for the past month. His pain happens at various times during the day with variable duration. His activity is less when his head hurts." *Id*. Dr. Cerjan diagnosed C.C. with "chronic headache" and ordered an MRI. *Id*. at 25. On the MRI order, Dr. Cerjan wrote, "head x 1 mo 3 per week." Pet. Ex. 12 at 1. Petitioner and C.C.'s father attended this appointment with C.C. and presumably gave the history to Dr. Cerjan. Pet Ex. 23 at 27 and Ex.2 at 22.

Petitioner argued that her second affidavit clarified that C.C. did not have headaches prior to the vaccination and that Dr. Cerjan did not separate the discussion of the cyst on the back of C.C.'s head and the onset of headaches. Pet. Response at 4; Pet. Ex. 29 at ¶¶ 2, 6. Further, petitioner argues that her expert, Dr. Chen also "cautions against the reliability of the [November 10, 2015 medical record] for the purposes of establishing the onset of symptoms," because Dr. Cerjan did not make any attempts to "delineate the onset of headaches as to the exact date or contextualize the headaches in the setting of C.C.'s parietal-occipital cyst." Pet. Response at 4. In Dr. Chen's supplemental report, she asserted that the "source of the onset of the headaches being one month appears to have originated by intake staff….and then pulled into Dr. Cerjan's notes," and that "it raised the possibility that [Dr. Cerjan] may have simply propagated any information provided at intake without probing for the accuracy of the onset." Pet. Ex. 35 at 1. However, the medical record from the November 10, 2015 appointment demonstrates that Dr. Cerjan probed for additional details about C.C.'s headaches, and he recorded those details under the "History of Present Illness." While Dr. Cerjan mentioned that C.C. had a "palpable, mobile nodule on the parietal, occipital first noted at six months," Dr. Cerjan took additional details about the duration, frequency and impact of C.C.'s headaches. He wrote, "[C.C.'s] pain happens at various times during the day with variable duration. His activity is less when his head hurts." *Id*. Dr. Cerjan diagnosed C.C. with "chronic headache." Pet. Ex. 2 at 25; Pet. Ex. 23 at 30. Further, this information appears to have been provided by petitioner herself.

These additional notations, coupled with the statement, "[C.C.] has been having headaches for the past month," Dr. Cerjan's diagnosis of "chronic headache," and his notation of "headache x 1 month, 3x per week" on the MRI order, provides significantly more detail than the mere onset statement in the initial intake form. Importantly, there is no reference at all to new onset of a severe headache that began one to two days prior to the appointment.

If C.C. had developed a new onset of a severe headache within one or two days of the appointment, as asserted by petitioner, it seems very likely that Dr. Cerjan would have recorded that history rather than the details about the C.C.'s headaches that he did note. As indicated above, Dr. Cerjan recorded that C.C. had a history of headaches for a month, occurring about three times a week, which occurred at various times and during which C.C.'s activity level decreased. Further, the cyst on C.C.'s scalp was mentioned at the November 10th appointment, as it had been in prior appointments. The cyst had apparently been the source of minor irritation in the past but had been diagnosed as essentially benign several years before. It is highly unlikely that the cyst would have been the reason that Dr. Cerjan ordered the MRI as demonstrated by the medical record which states, "Will do MRI for *headaches."* Pet. Ex. 2 at 25 (emphasis added). Headaches that cause a reduction in activity arise within the skull and quite logically persistent headaches would be a reason for ordering an MRI of the brain as Dr. Cerjan did. Thus, it appears that Dr. Cerjan distinguished the cyst on the back of C.C.'s head from the headache symptoms and indeed the MRI demonstrated multiple lesions in the brain that certainly could give rise to headaches.

The next medical record was from C.C.'s appointment on December 16, 2015, with neurologist, Dr. Ferreras. Pet. Ex. 3 at 7. C.C. was accompanied by both parents and his maternal grandmother. *Id*. In the "History of Present Illness" it stated, "….[C.C] is here for further evaluation of abnormal behavior taken in 11/2015." *Id*. It continued, stating, "The

reason that led to brain MRI testing as mom indicated is-[C.C] was in preschool this year and had to be pulled out by October 2015, because of behavioral problems…." *Id.* Dr. Ferreras noted that [C.C] "has poor impulse control and started rubbing his head in the back. He also has a history of headaches, intermittent crossing his eyes. Mom also noticed that sometimes he is off balance." *Id.* After reviewing C.C.'s MRI and a physical exam, Dr. Ferreras diagnosed C.C. with abnormal MRI, which in her opinion, "could be a finding of past infection, vs. demyelinating conditions from a progressive disease…encouraging that he has not shown clear regression." *Id.* at 10. Then Dr. Ferreras wrote that, "[C.C.] has headaches and personality changes which may or may not be related to his MRI findings." *Id.* at 10. The medical history recorded at this appointment, attended by multiple adults, clearly states that C.C. was taken out of school in October 2015 because of behavioral problems. While the specific date in October 2015 was not provided, it would mean that C.C. was not in school on November 9th, when petitioner stated in her affidavits that she picked him up from school, and he was suffering a new onset of a severe, "all over" headache. Thus, this medical record also provides evidence that C.C.'s behavioral changes likely began prior to the October 30, 2015, vaccination, and contradicts petitioner's affidavits that C.C. was picked up on November 9, 2015, from preschool. Further, the description by Dr. Ferreras, while brief, was generally consistent with the facts recorded by Dr. Cerjan.

When C.C. was evaluated by ENT, Dr. Elliott McKee on January 29, 2016, the reason for the visit was noted as, "Problem-brain lesion history, eyes are crossing, [headache], location-OU, (both eyes) quality-crossing or drifting, duration has been going on for over four months, timing-intermittent, severity-worsening." *Id.* Under the Review of Systems, there is a "Psychiatric," section where petitioner (who accompanied C.C. to this appointment) denied ADD, ADHD, anxiety, depression, or behavioral problems. *Id.* at 4. Again, at this appointment, petitioner provided the medical history to the provider, and petitioner reported that C.C.'s "eye drifting," and headaches were going on for over four months, suggesting that the headaches and eye drifting had begun in early October, which is prior to the vaccination of October 30, 2015.

The first reference in the medical records that C.C.'s headaches began after the flu shot was in the history given to Dr. Gualtieri on February 26, 2018-- more than two years post vaccination. Pet. Ex. 19 at 10. Under "Chief Complaint/HPI" Dr. Gualtieri wrote, "Immediately following a flu-shot, [C.C.] started having headaches in 2014; they saw Dr. [Ferreras] and he had a comprehensive work-up, including genetic testing, two MRIs, and a neuropthalmologist. He has lesions in the frontal and occipital lobes that are believed to be related to the flu shot." *Id.* Dr. Gualtieri wrote, "The clinical picture is one of attention deficit/hyperactivity disorder, but atypical attention deficit/hyperactivity disorder in a very smart child. It may or may not be related to brain injury." *Id.* Of course, the appointment with Dr. Gualtieri was two years after the vaccination, and the record contains multiple errors. For example, he referenced the flu shot occurring in 2014, not 2015. Further, he stated that C.C. had lesions in the occipital lobe. Pet. Ex. 19 at 10. C.C.'s MRI from November 20, 2015, stated, "No significant involvement of the temporal or occipital lobes…." Pet. Ex. 21 at 1.

Finally, other than the records from Dr. Gualtieri, none of the other medical records associate the onset of C.C.'s headaches or behavioral problems to the October 30, 2015, flu shot. *See* Pet. Ex. 23 at 23 (appointment dated June 13, 2016, noting that C.C. had significant behavior

problems in Pre-K with Vanderbilts + ADHD on teacher and parent forms); Pet. Ex. 23 at 22 (C.C. diagnosed with fever and acute pharyngitis on November 7, 2016); Pet. Ex. 23 at 14 (C.C. evaluated for a routine child wellness exam on June 14, 2017, and continued diagnosis was ADHD). Significantly, none of the records describe a sudden onset severe headache occurring on or about November 9, 2015.

To provide corroborating evidence that C.C.'s headaches began after the vaccine at issue and consistent with the timeline petitioner provided in her affidavits, petitioner sought to secure C.C.'s school records. *See* Rule 5 Order. After multiple attempts to obtain the school records from Amazing Kids Childcare Center, which had closed, petitioner was able to file a letter from Ms. Stephanie Hopper, the owner of Amazing Kids daycare. Pet. Ex. 37. In this letter, Ms. Hopper wrote that C.C. had been withdrawn from Amazing Kids in October 2015 due to behavioral issues. *Id.* Ms. Hopper stated, "From my memory [C.C] left during the month of October 2015 to attend Grace Christian Academy. Based on my memory, [C.C.'s] mother moved him to Grace Christian Academy because of his behavior, mother wanted to see if they could help with his behavior issues." *Id.* Further, Ms. Hopper wrote that she did not recall exact dates regarding C.C.'s behavior because "all records of enrollment, withdrawing, attendance and discipline were all given to parents when the childcare center closed in December 2015." *Id.* Ms. Hopper recalled that C.C.'s behavioral issues would "consist of anger outrages, throwing chairs, cussing." *Id.* She reiterated that all records of major behavioral issues, along with verbal conversations with parents in reference to a child's behavior, were given to parents at the time the childcare center closed in December 2015." *Id.* No additional records from Amazing Kids were filed.

While Ms. Hopper explained that she was writing from memory, her recollection that C.C. was withdrawn from Amazing Kids Childcare Center in October 2015 is consistent with C.C.'s medical records. More specifically, it corroborates the history that is recited in the medical record from C.C.'s appointment with Dr. Ferreras on December 16, 2015, which provides, "[C.C.] was in preschool this year and had to be pulled out by October 2015, because of behavioral problems." Pet. Ex. 3 at 7.

Furthermore, C.C.'s appointment with neurologist, Dr. Ferreras noted that he had been experiencing behavioral issues that at least had developed by October 2015. Dr. Ferreras wrote, "He was in preschool this year and has to be pulled out by October 2015 because of behavioral problems." Pet. Ex. 3 at 7. The history provided to Dr. Ferreras, again by petitioner herself, was consistent with Ms. Hopper's account of when and why C.C. left Amazing Kids preschool. While Ms. Hopper wrote that she was writing from memory, the letter was consistent with what was recorded in the contemporaneously created medical record from December 16, 2015.

The only contradictory evidence submitted by petitioner was her two affidavits, which were created three and four years after the medical appointments referenced above, and the records from Dr. Gualtieri created over two years post vaccination. The history provided by petitioner to Dr. Gualtieri was given to him by petitioner less than one month before she filed this petition.

The Federal Circuit has recognized the importance of contemporaneous medical records with histories provided for purposes of treatment. "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d at 1528. In *Kirby*, the Federal Circuit clarified that medical records are not presumptively accurate and complete as to all [of a] patient's physical conditions. *Kirby v. Sec'y of Health & Human Servs*, 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). The Circuit held that a reasonable fact finder could find that petitioner's testimony of ongoing pain did not conflict with the records as the records are also silent about the *nonexistence* of such symptoms. *Id.* at 1383. Further, the Circuit acknowledged that the silence in the records could be explained by the fact that petitioner had exhausted all available treatment. *Id.*

This case, however, does not involve medical records that are silent to the existence of a condition, as they were in *Kirby*. In *Kirby*, the special master found that the petitioner's testimony did not conflict with medical records that were "silent about the existence of any lingering symptoms." *Kirby*, at 1382. Instead, this case presents a fact pattern similar to *Cucuras*. In *Cucuras*, the petitioners testified that their daughter's seizures began one day after receiving the DPT vaccination. 993 F.2d at 1527. However, the contemporaneous medical records repeatedly recorded that the child's symptoms did not present until at least one week after the DPT vaccine. *Id.* at 1527-28. The special master denied compensation, affording more weight to the medical records, than the testimony that conflicted with the "contemporaneous documentary evidence." *See Kirby*, at 997 F.3d at 1382. The Federal Circuit clarified that, "it was not erroneous to give greater weight to contemporaneous medical records than to later, contradictory testimony." *Id.*

Here, the contemporaneously created medical records consistently describe the onset of C.C.'s headaches and behavioral issues as preceding the October 30, 2015 flu shot. Further, the medical appointments in November 2015, December 2015, and January 2016, were focused on the condition for which treatment was sought, and therefore, it is difficult to conceive that petitioner would not have provided the doctors with accurate information about C.C.'s condition, particularly if, as claimed, the child developed a severe headache in the day or two before the November 10, 2015 appointment. Finally, the letter from Ms. Hopper, provided by petitioner, described the onset of C.C.'s behavioral issues and withdrawal from Amazing Kids consistent with the contemporaneously created medical records. Thus, the medical records in this case, are afforded more weight than petitioner's contradictory statements provided in her affidavits, and the one medical record created two and half years after the vaccination at issue.

The Vaccine Act expressly bars the court or a special master from [finding a fact] "based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). Given the weight afforded to the contemporaneous medical records, which appear to be clear and consistent, and the importance of providing accurate information to a treating physician, I cannot accept the contradictory version of the facts asserted by the petitioner in the petition and her affidavits. To accept the subsequent version of facts in petitioner's affidavits would require me to disregard all the consistent, contemporaneously created medical

records and accept a contradictory history. This I will not do. As such, I find that there is preponderant evidence that C.C.'s neurological symptoms began before the October 30, 2015, flu vaccination, and thus could not have been caused by the vaccine.[17] As such, it is necessary to dismiss the petition.

Respondent's motion is hereby **GRANTED,** and this petition is **DISMISSED.**

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master

[17] *See Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) (holding that the *Althen* analysis is inapplicable when the Special Master found that the illness was present before the vaccine was administered.)